



ASX Announcement

Race Investor Update

15 July 2020 – Race Oncology Limited (“Race” or “the Company”) (ASX: RAC) is pleased to release an updated investor presentation. It summarises significant recent news in regards the clinical development of our lead oncology drug, bisantrene. This update covers:

- The recently reported investigator-led *bisantrene for relapsed/refractory Acute Myeloid Leukaemia* Phase II clinical trial, through which the investigators observed an impressive 40% clinical response rate in hard to treat R/R AML patients who had failed an average of three prior lines of therapy
- The central role the Fat mass- and obesity-associated (FTO) protein has in the proliferation of a wide range of cancers and how bisantrene has been identified as a potent FTO inhibitor in a recent independent preclinical study by investigators from the City of Hope Hospital in Los Angeles, USA.
- A review and update of the 5-path strategy for bisantrene and associated potential market opportunities.
- An update on expected near term clinical and preclinical news.

A copy of the presentation is appended with this cover note.

- ENDS -

About Race Oncology (RAC: ASX)

Race Oncology (RAC) is a drug development biotech with a Phase II/III cancer drug called bisantrene. RAC has compelling clinical data for Bisantrene in acute myeloid leukaemia (AML) as well as breast and ovarian cancer. RAC is pursuing an exciting ‘5-Path’ clinical development strategy that involves parallel US and Australian clinical trials in AML, breast and ovarian with clinical trials to begin in 2020.

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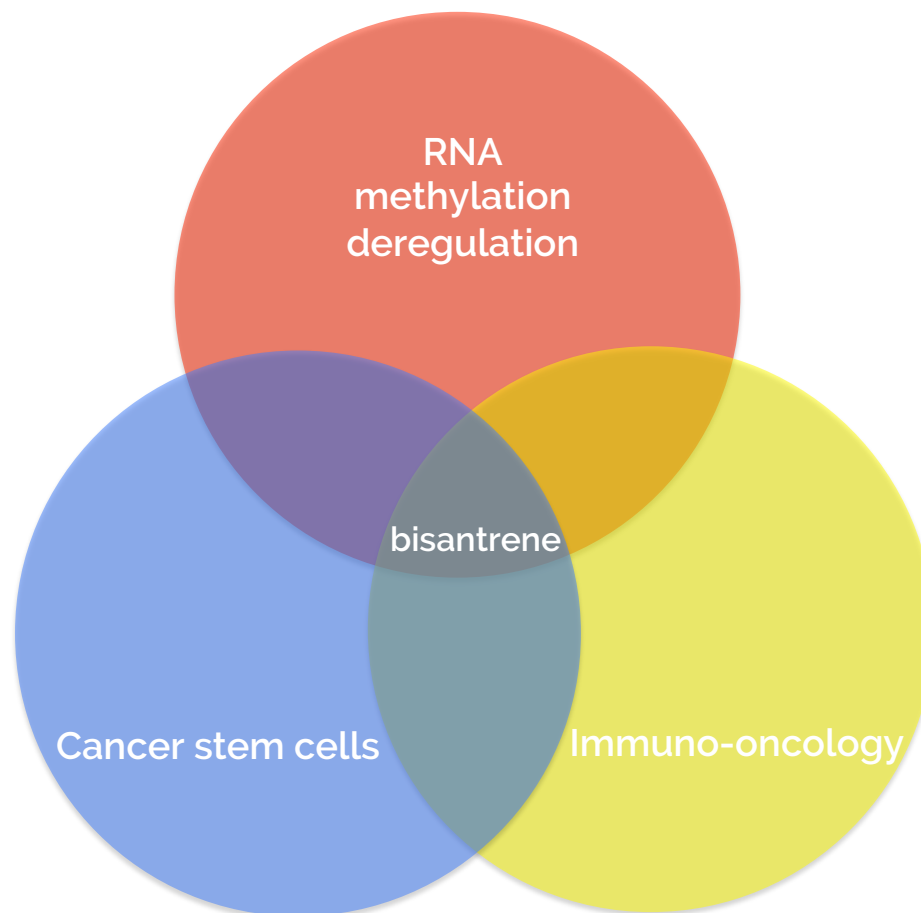


Investor Update | July 2020



Investment highlights

- June 2020
 - Independent **Phase II trial bisantrene is safe, well tolerated and efficacious** beyond expectations in a very hard to treat relapsed / refractory Acute Myeloid Leukaemia (R/R AML) population
 - Independent preclinical study identify bisantrene as a potent FTO inhibitor **placing bisantrene in three of the hottest areas of oncology**
- 5-path strategy offer a **derisked opportunity to bring bisantrene into multi-billion dollar markets**
- Strong Board and KOL clinical advisors
- Well funded and backed by biotech specialist investors



Corporate snapshot

SHARES ON ISSUE	
Shares issued ¹	119.8 m
Options issued	36.5 m
Shareholders (14 Jul '20)	1537
MARKET CAPITALISATION	
Share price (14 Jul '20)	\$1.02
Market value (14 Jul '20)	\$122.2 m
Cash (14 Jul '20) ²	\$4.7 m
Enterprise value (EV)	\$117.5 m
SIGNIFICANT SHAREHOLDERS	
Bill Garner (NED)	11.23%
Daniel Tillett (Director & CSO)	7.54%
Total shares held by directors	23%

1. Minus proposed 2.2 million share cancellation (ASX Announcement 10 July 2020)
2. Including \$3 million strategic placement (ASX Announcement 13 July 2020)



Race management and advisors

seasoned team, key opinion leaders

BOARD



*Dr John Cullity,
Exec. Chair*

sanofi aventis

Schering-Plough

TORREYA

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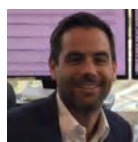


Dr Bill Garner NED

EGB Ventures
Global life science investments

InMed
Pharmaceuticals

DelMar
PHARMACEUTICALS



Mr Chris Ntoumenopoulos, NED

citigroup

CPSCapital

indianocean
specialist growth and corporate solutions

BOARD



*Dr Daniel Tillett
Exec. Dir. / CSO*

NUCLEICS

LA TROBE
UNIVERSITY



*Prof Borje Andersson,
NED*

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center
Making Cancer History

UNIVERSITY of
HOUSTON
COLLEGE OF PHARMACY



Mr Phil Lynch, NED

Johnson & Johnson

AUSTRALIAN
FOOD &
GROCERY
COUNCIL

SCIENTIFIC ADVISORS



*Prof Borje Andersson,
MD Anderson*

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center
Making Cancer History

UNIVERSITY of
HOUSTON
COLLEGE OF PHARMACY



*Prof Jaap Boelens
MSKCC*

MSK Kids
Memorial Sloan Kettering

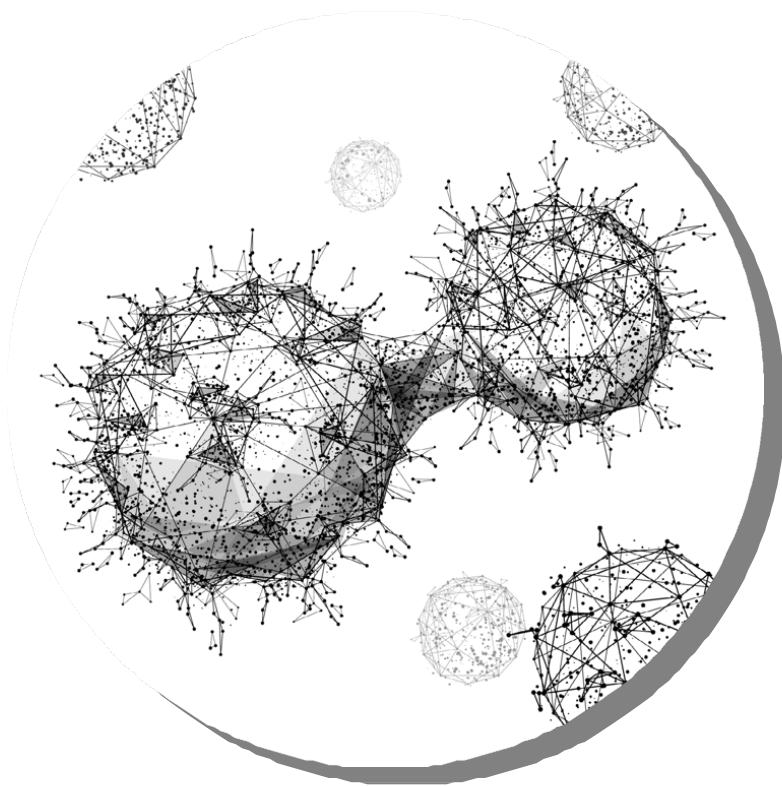
UMC Utrecht



Prof Didier Blaise, Paoli Calmette

Aix-Marseille
université

INSTITUT PAOLI-CALMETTES
UNICANCER Marseille



About Bisantrene

Bisantrene is a cancer chemotherapy drug developed in the 1980s by Lederle Pharmaceuticals

Bisantrene was tested in more than 40 human trials and showed activity in AML (acute myeloid leukaemia), as well as breast and ovarian cancer

Bisantrene was approved for AML in France in 1988, but never commercialised and it disappeared in the 1990s

Race was founded in 2016 with the mission to rescue bisantrene and bring this valuable drug back into clinical practice

Since then, Race has:

- Successfully manufactured bisantrene (GMP)
- Built a strong patent position (4 granted)
- US Orphan Drug designation (7 years exclusivity)
- Secured Rare Paediatric Disease (RPD) designation with the potential to receive a Priority Review Voucher (PRV)



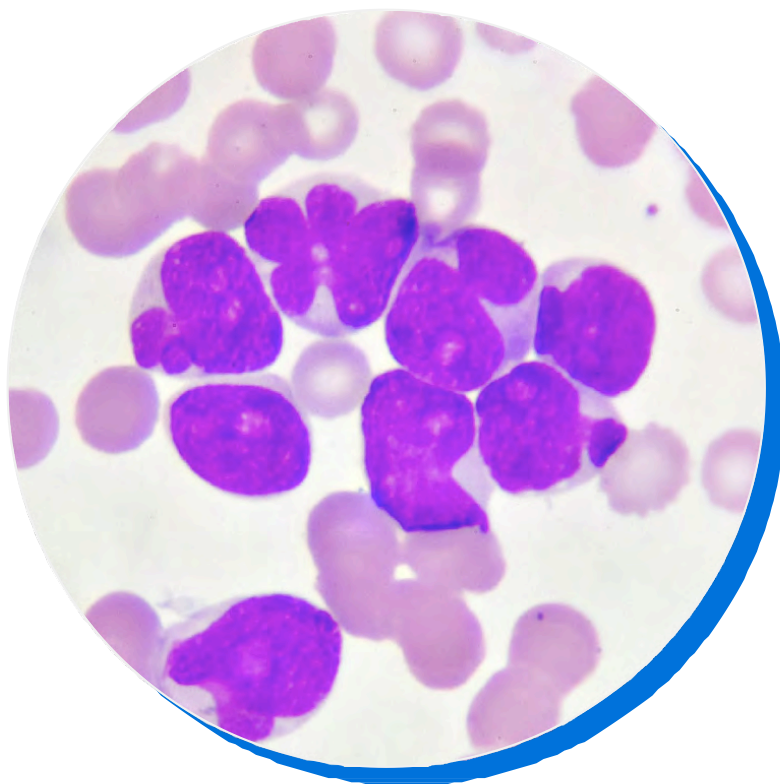
June 2020

pivotal for bisantrene & race

Results of the Phase II
bisantrene clinical trial
at the Sheba Medical
Center (Israel)

Identification by Su *et al*
(City of Hope Hospital,
USA) that bisantrene is a
potent inhibitor of FTO

Phase II Bisantrene monotherapy in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML)



Phase II bisantrene trial study design



Phase II open-label single arm single center study (NCT03820908)

- 7 day 250mg/m²/day
- n=10 R/R AML patients
- Single cycle of treatment
- Study population heavily pre-treated (average of 3 prior treatments)



Chaim Sheba Medical Center, Tel Aviv, Israel

- Principal investigator. Professor Arnon Nagler



Phase II bisantrene trial results¹



Of the 10 patients, one patient (10%) achieved a complete remission and three patients achieved partial remissions



Overall Response Rate of 40%

All 4 responders had high-risk extramedullary disease

- Patient with leukaemia cutis (skin) achieved CR and bridged to allogeneic stem cell transplantation
- Patient with breast chloromas achieved high reduction in sites of disease deemed as partial response
- Patients with CNS disease both achieved transient clearance of peripheral blood blasts with one resulting in partial remission of ocular disease and other partial response of CNS disease



High levels of safety and no unexpected toxicities

1. ASX Announcements 16 & 19 June 2020





Next steps

Bisantrene combination AML trial



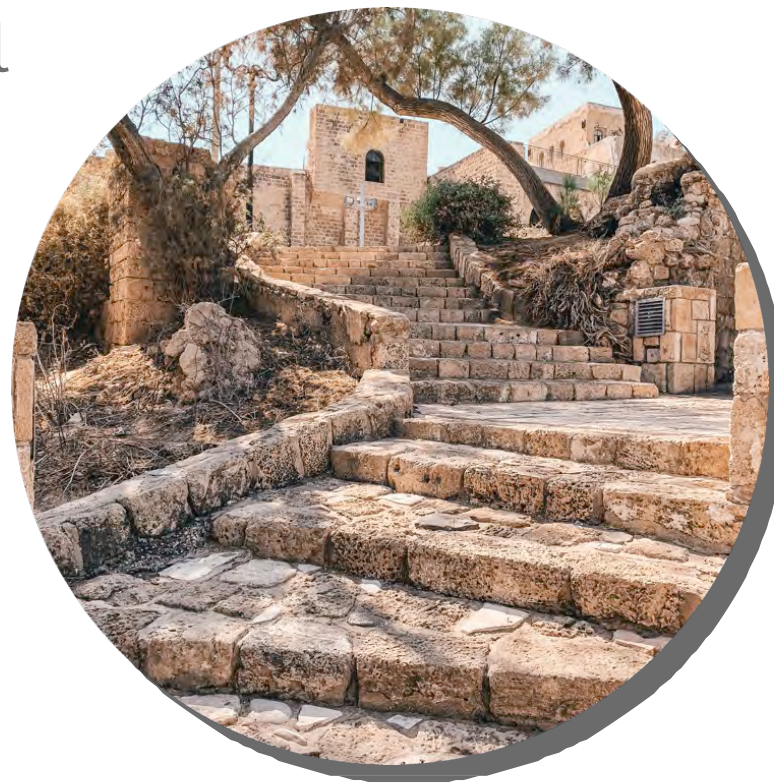
Follow-up study combining bisantrene with other anti-leukaemic drugs is currently in advanced planning



Trial planned to begin recruitment late 2020



Trial fully funded via \$3 million strategic placement to biotech investors¹



1. ASX Announcement 13 July 2020

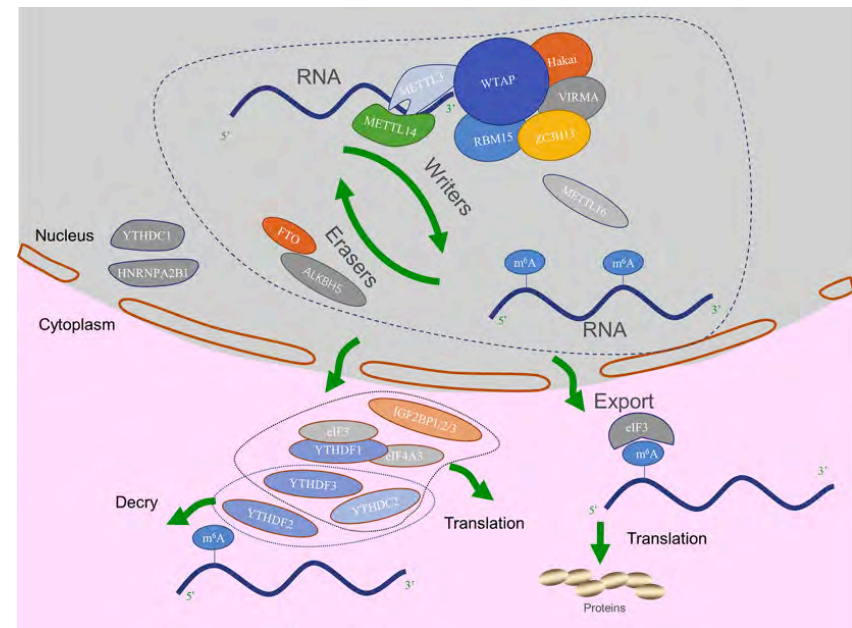
A microscopic image of tissue cells, likely from a histological section, showing various cell types and structures. The image is overlaid with a semi-transparent dark rectangle containing the title text.

The critical role of RNA m⁶A methylation in cancer

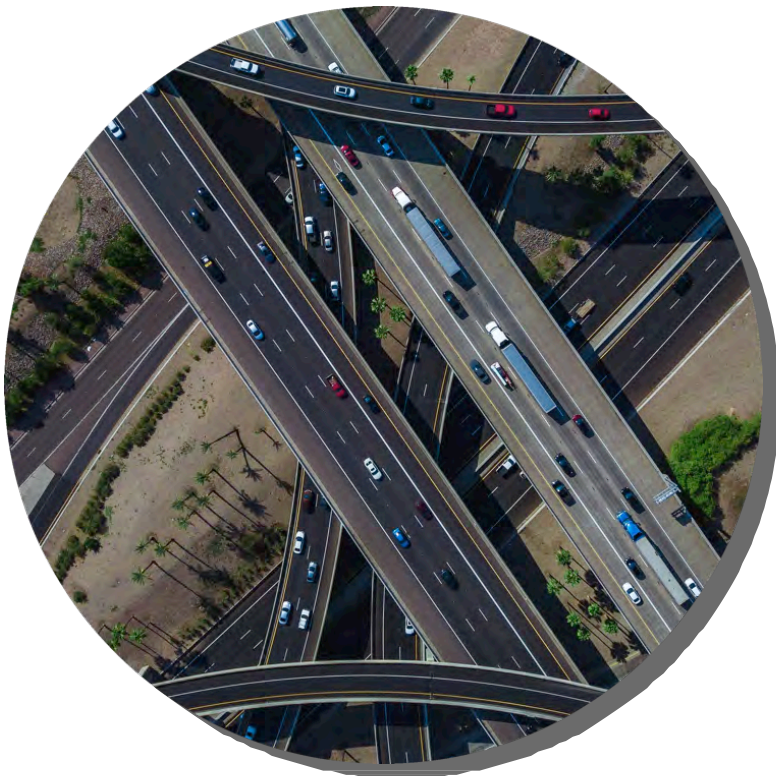
m⁶A RNA methylation

key pathway in cancer

- Scientific discoveries over the last decade have identified dysregulation of RNA methylation as a key driver of cancer development^{1,2}
- Changes in m⁶A RNA methylation control the expression of key genes in cancer development and growth
- Very widespread mechanism across a wide range of different cancers including **leukemia, breast, lung, ovarian, gastric, brain, melanoma, pancreatic, etc** – *hard to find a cancer type where RNA methylation dysregulation is not important*
- **One of the hottest areas of cancer research**



1. Lan, Q., Liu, P. Y., Haase, J., Bell, J. L., Hüttelmaier, S., & Liu, T. (2019). The Critical Role of RNA m6A Methylation in Cancer. *Cancer Research*, 79(7), 1285–1292.
2. Zhao, W., Qi, X., Liu, L., Ma, S., Liu, J., & Wu, J. (2020). Epigenetic Regulation of m6A Modifications in Human Cancer. *Molecular Therapy - Nucleic Acids*, 19, 405–412.



FTO

central player in cancer

- Fat mass- and obesity-associated Protein (FTO)¹
- Variations in the gene are associated with body weight differences¹
- Found in 2011 to be a m⁶A RNA demethylase (removes methyl groups from RNA)
- Regulates the level of m⁶A methylation in RNA¹
- Increases in the expression of FTO protein drive cancer development and metastasis
- **Reduction of FTO activity kills or slows the growth of a wide range of cancers²**

1. Deng, X., Su, R., Stanford, S., & Chen, J. (2018). Critical Enzymatic Functions of FTO in Obesity and Cancer. *Frontiers in Endocrinology*, 9, 724–7
2. Huang, H., Weng, H., & Chen, J. (2020). m⁶A Modification in Coding and Non-coding RNAs: Roles and Therapeutic Implications in Cancer. *Cancer Cell*, 37(3), 270–280

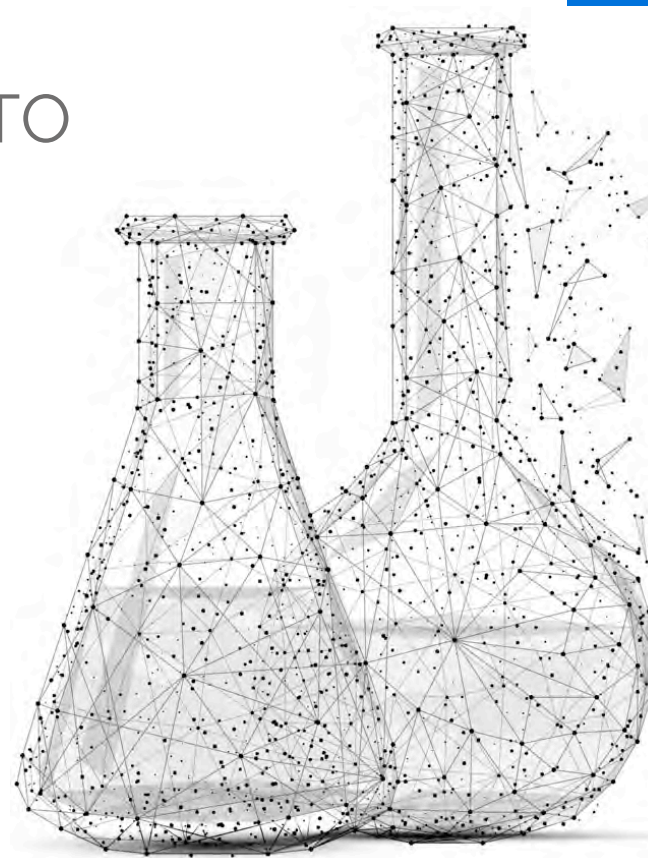


June 2020 City of Hope Study

Bisantrene is a potent inhibitor of FTO

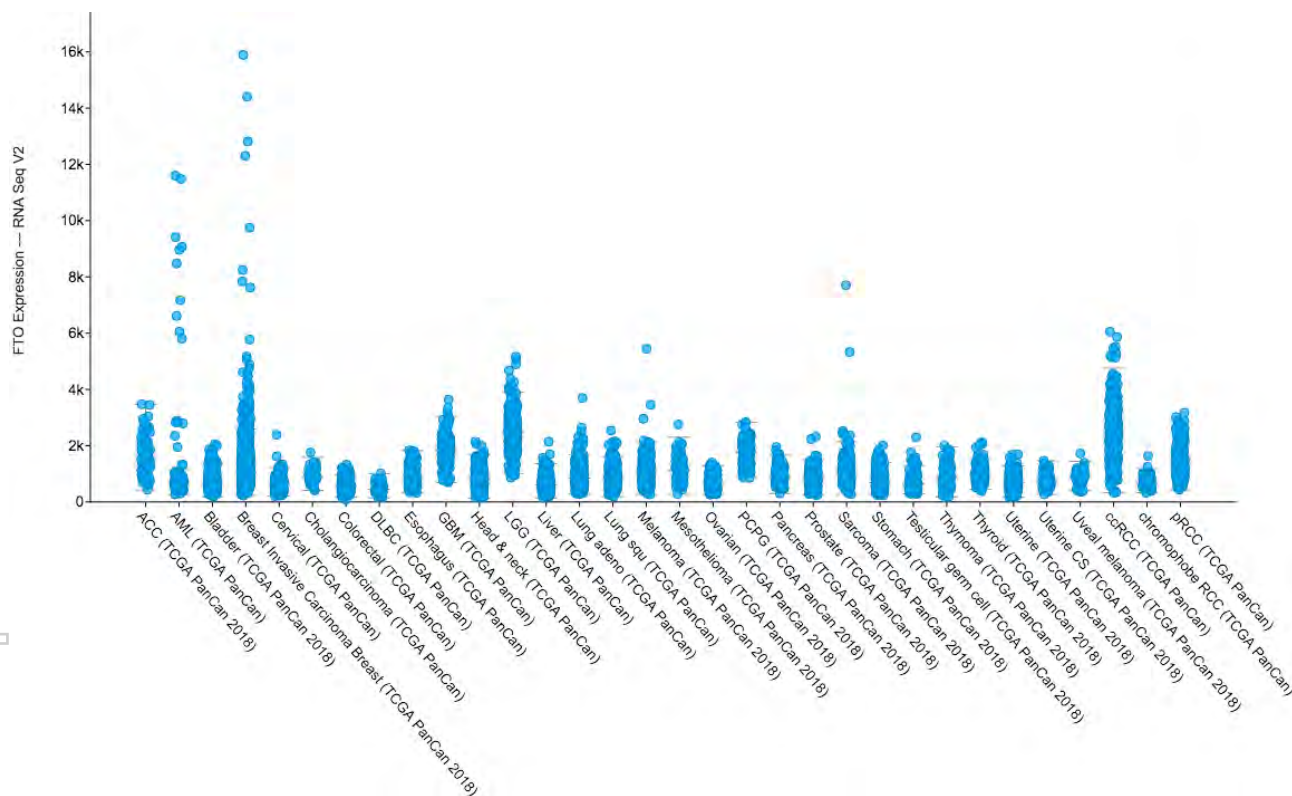
- Su *et al* from the City of Hope Hospital (Los Angeles) discovered that **bisantrene** is a **potent inhibitor of FTO** (IC₅₀ = 142nM)¹
- Extremely impressive and high quality work published in the top tier cancer journal *Cancer Cell*
- Screened 260,000 compounds from the NCI DTP library – **found bisantrene**
- **Bisantrene was the most specific FTO inhibitor identified** to date and more than 10x better than any previous known drug – **targeted agent**
- In a preclinical mouse model of AML bisantrene was shown to be a potent anti-leukemic at very low doses (7.5mg/m²/day)
- Bisantrene inhibits cancer stem cell renewal (stem cell oncology)
- Bisantrene sensitizes AML cells to T-cell cytotoxicity and overcomes immune evasion (immuno-oncology)
- Places bisantrene right in the middle of three of the hottest area in oncology
 - RNA methylation
 - Cancer stem cells
 - Immuno-oncology
- Bisantrene is no longer a boring old chemo drug!

1. Su, R., Dong, L., Li, Y., Gao, M., Han, L., Wunderlich, M., et al. (2020). Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion. *Cancer Cell*.





What does this all mean for Race?



- **Bisantrene still works**
- Validation of the historical data and our 5-path strategy for commercialisation
- **Bisantrene has two mechanisms of action**
 - **High dose** anthracycline-like chemotherapeutic (250mg/m²/d) but with greater safety with less cardiotoxicity (clinical data)
 - **Low dose** (7.5mg/m²/d) FTO targeted agent with low toxicity (preclinical data)
- Preclinical data opens up opportunities for bisantrene in other cancer types where FTO is overexpressed
- Has already attracted keen interest from key opinion leaders in oncology (potential collaborations)
- Race's IP position unchanged and robust



AML

a crowded market?

- AML is increasingly a crowded market with more than 200 new treatments in development
- Any new AML treatment needs to **establish a market niche with less competition**
- Race is using three commercialisation strategies
 - Aim to replacing doxorubicin in high intensity induction chemotherapy using an clinical development approach similar to that used by Jazz with Vyxeos®
 - Open new areas for investigation not served by existing AML treatments (e.g. MRD)
 - Target pediatric AML to secure a valuable PRV

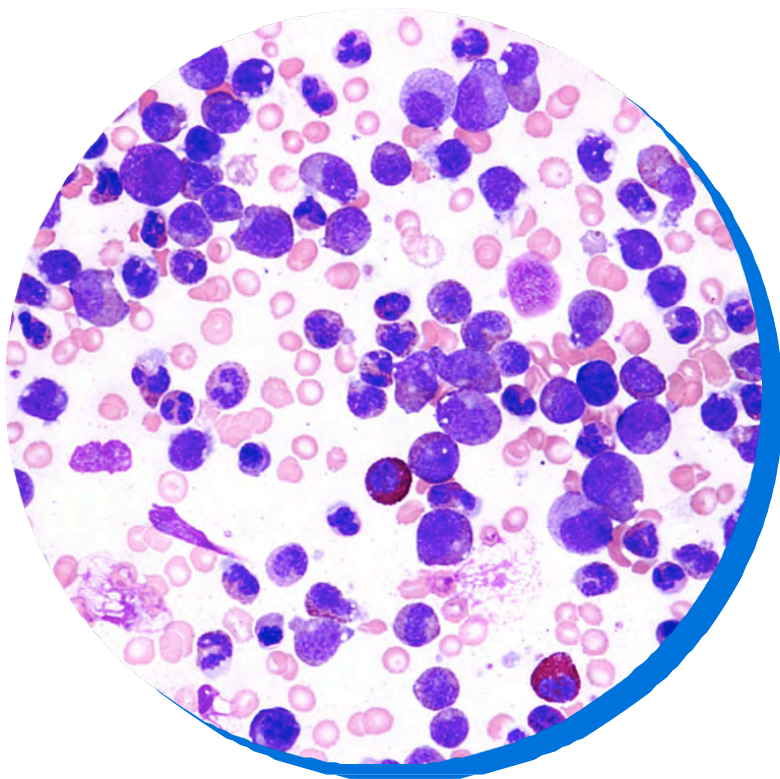




The combination opportunity

Previous research (Lederle/NCI) showed that Bisantrene has differential activity over other chemotherapy agents

How does it stack up today using modern research techniques?



Bisantrene adult R/R AML trial



Phase I/II Bisantrene combination AML study
Bisantrene plus other approved AML treatments



Plan to run trial in Israel
Familiar with bisantrene
Does not require FDA Investigator New Drug (IND) approval



Eligibility
All AML patients after first relapse or refractory



Endpoints
Pharmacokinetics, dosage and safety of the drug combination
CR and progression free survival



Goals
Attract partner support for US trial
Support paediatric trial IND



Bisantrene paediatric AML trial



Phase I/II paediatric AML Bisantrene combination study
Bisantrene plus other approved AML treatments



Aim is to run trial in US and Australia under IND
Small trial – expect 25-40 patients



Eligibility
Childhood AML patients who meet 'rare paediatric disease' criteria under Race's RPD/PRV designation

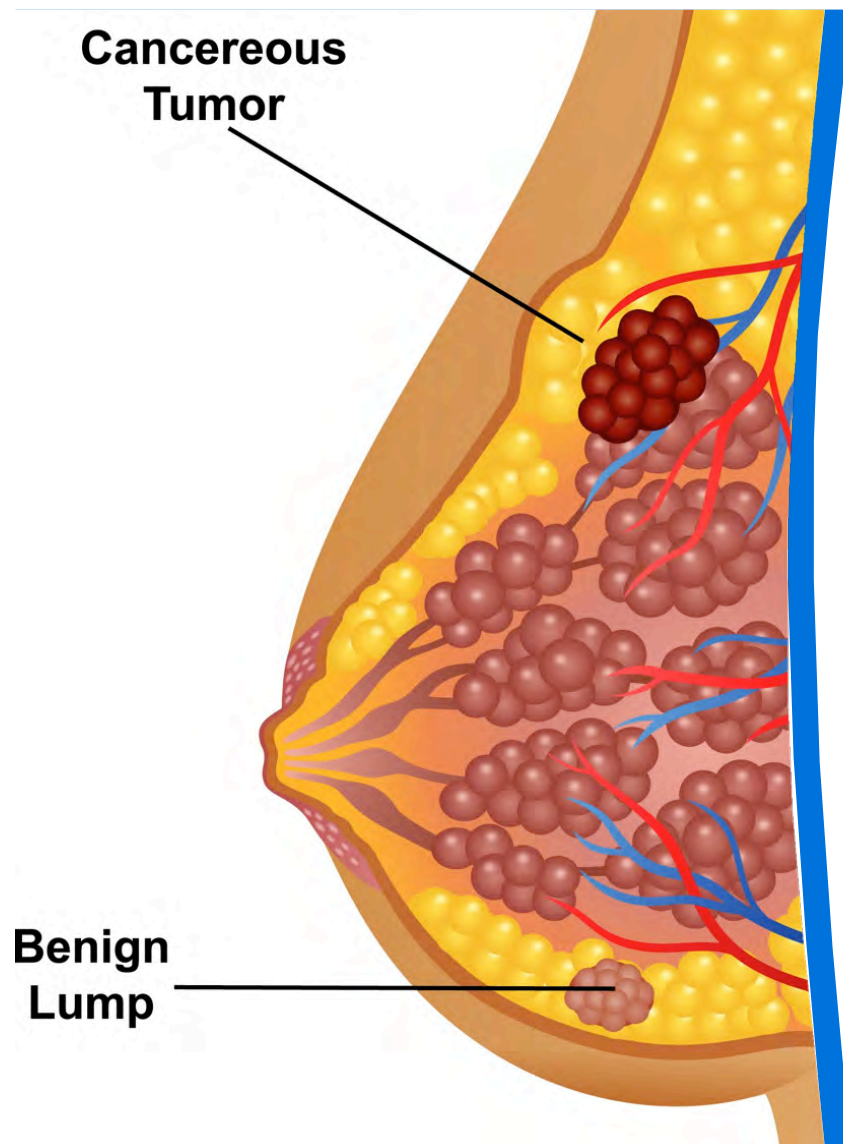


Endpoints
Pharmacokinetics, dosage and safety of the drug combination in children
CR and progression free survival



Goal
Gain approval for Bisantrene for Rare Pediatric Disease and secure PRV
PRVs can be sold on secondary market (range US\$75-\$150 million)





Breast cancer combination trial



Phase I/II proof-of-concept (POC) trial in breast cancer

Will use drug combinations which preclinical data show synergise with Bisantrene (preclinical studies underway with U. Newcastle)



Use optimal dosing, administration and combination of Bisantrene

Historical breast cancer trials used sub-optimal dosing and administration of Bisantrene (but still showed good activity!)



Goals

Opens up much larger cancer market than AML
(2 million cases each year)

Show equivalent efficacy to existing treatments but with fewer serious side effects (less damage to the heart)

Displace the current anthracyclines used in breast cancer treatment



Ovarian cancer combination trial



Phase I/II proof of concept (POC) trial in ovarian cancer

Preclinical trials to be performed to identify which drug combinations show synergy



Use optimal dosing, administration & combinations of Bisantrane

Historical non-AML cancer trials all used sub-optimal dosing and did not use combinations, but still showed activity for Bisantrane

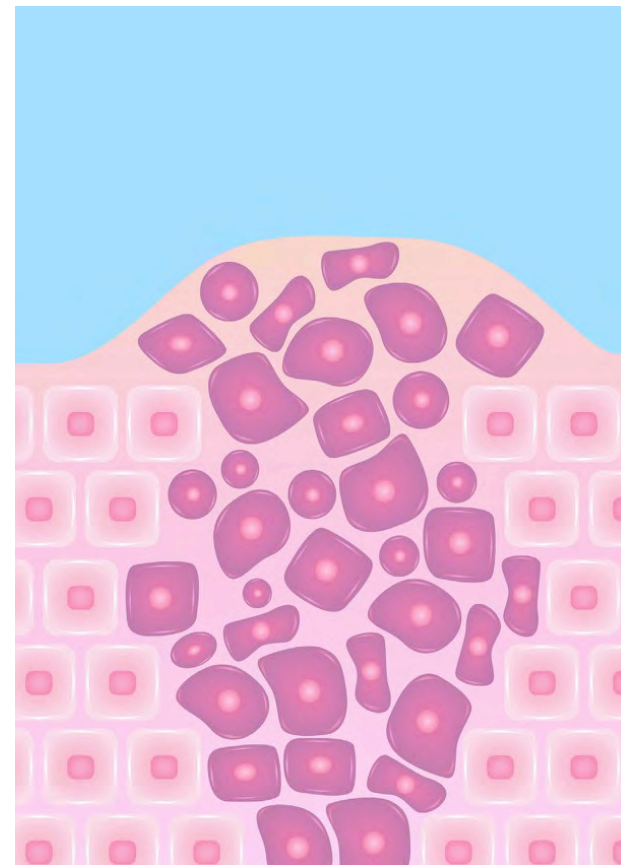


Goals

Open up much larger cancer market than AML

(200,000 cases each year)

POC trial to attract pharmaceutical partner for approval trials



Recent clinical studies have demonstrated the importance of eliminating measurable residual disease (MRD) in AML patients

Why is MRD so important for curing AML patients and what can be done?

The MRD opportunity



The MRD opportunity

Up to 80% of AML patients who are fit enough for induction chemotherapy (3+7) will go into remission (CR) and may then be candidates for a human stem cell transplant (HSCT)

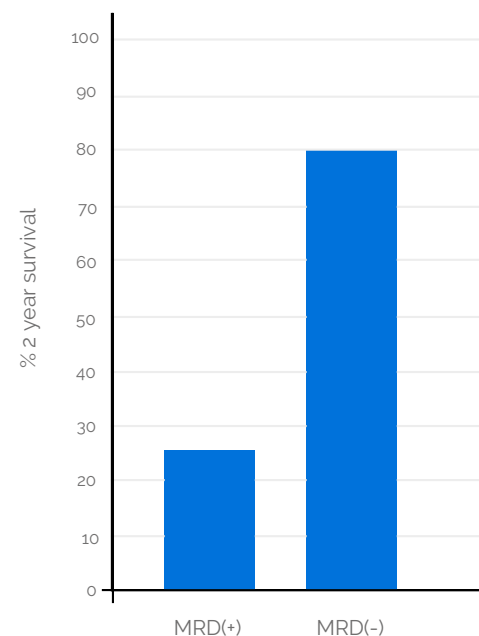
Whether the transplant is successful depends largely on the patient's MRD (Measurable Residual Disease) status at the time of transplant

- MRD(+) patients (those with MRD) have less than 25% two-year survival time
- MRD(-) patients have a 80% survival post transplant = potential cure!

As yet, there are no approved treatments that can change MRD status from (+) to (-) for AML

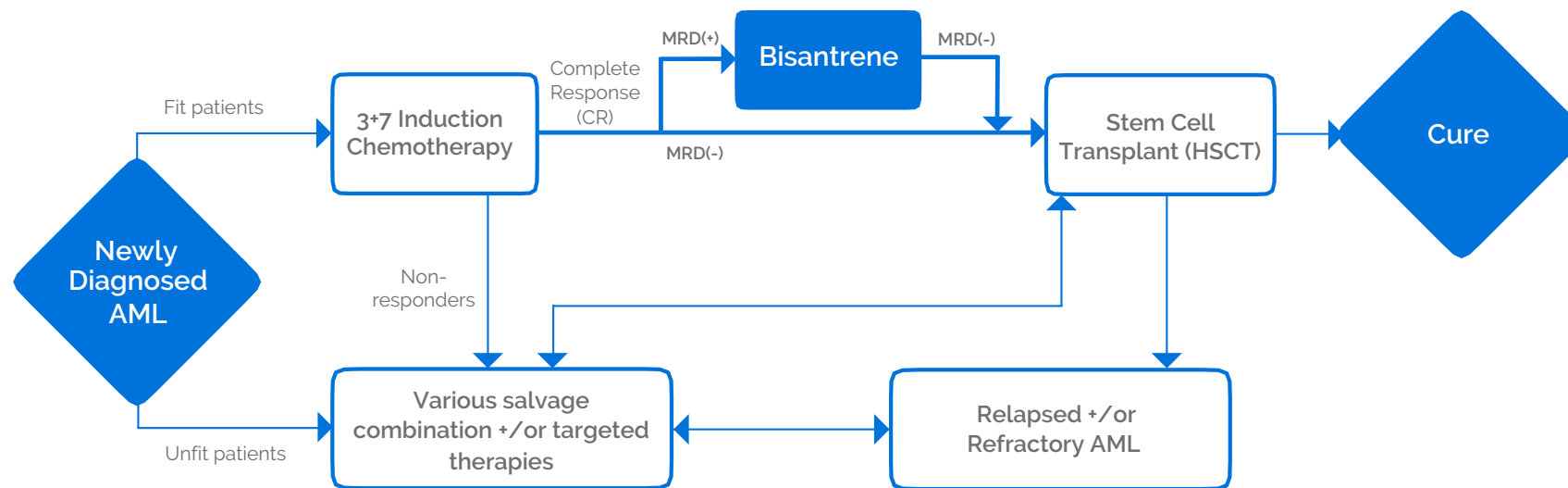
- Bisantrene is potentially the answer
- ~3500 case per year (USA)

2-year survival and residual disease status at transplant



Bisantrene in AML treatment for MRD

Bisantrene could transform cure rates by changing MRD status





Phase II MRD trial



Phase II study of Bisantrene treatment after (7+3) induction chemotherapy to change MRD status

Aim to run trial in USA and/or Israel/Australia in partnership with leading US cancer centers



Eligibility

Transplant eligible MRD(+) patients in CR after induction chemotherapy – potential for paediatric study too



Study Design

Open label 7-day Bisantrene 250mg/m²/day treatment in 28 MRD(+) patients



Endpoints

MRD status post-Bisantrene
Treatment post-transplant survival



Goal

Early FDA approval of Bisantrene for MRD(+) patients





Near term activities

- Initiation of Phase II combination AML trial
- Preclinical breast cancer results
- AML drug combination publication
- Sheba Phase II AML publication
- ASH presentation (conference abstract)
- FDA Investigation New Drug (IND) submission
- Potential for other investigator initiated trials





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Selected oncology buyout transaction leukaemia

Company	Drug	Value	Date	Phase
Forty Seven ¹	magrolimab	US\$4.9 billion	2020	I/II
Ariad ²	brigantinib	US\$5.2 billion	2017	II
Celator Pharma ³	CPX-351 (Vyxeos®)	US\$1.5 billion	2016	III
Micromet ⁴	blinatumomab	US\$1.16 billion	2012	II
Ambit Biosciences ⁵	quizartinib	US\$0.41 billion	2014	II
Average		US\$2.64 billion		

1. www.gilead.com/news-and-press/press-room/press-releases/2020/3/gilead-to-acquire-forty-seven-for-49-billion
2. endpts.com/takeda-grabs-ariad-expands-oncology-portfolio-in-5-2b-buyout/
3. www.forbes.com/sites/lukeimmerman/2016/05/31/celator-gets-bought-seeing-stock-rocket-from-1-68-to-30-25-in-two-months
4. investors.amgen.com/news-releases/news-release-details/amgen-acquire-micromet
5. www.fiercebitech.com/financials/daiichi-sankyo-bags-leukemia-drug-410m-ambit-buyout



AML case study 1

ivosidenib



Approved by the FDA in May 2019 for newly diagnosed AML with a susceptible IDH1 mutation¹

Early approval from a Phase I/II open label trial of 28 patients
43% CR/CRi²



Small Market

700 – 1100 patients in the USA per year



Total Sales

US\$300 million per year³

1. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-first-line-treatment-aml-idh1-mutation>

2. <https://clinicaltrials.gov/ct2/show/NCT02074839>

3. <https://www.fiercebiotech.com/special-report/20-tibsovo>





AML case study 2

gilteritinib



Approved by the FDA in November 2018 for relapsed or refractory AML with a FLT3 mutation¹

Early approval of gilteritinib based on an interim analysis of the ADMIRAL trial²

138 adult patients having a FLT3 ITD, D835, or I836 mutation
CR/CRi **~21%**



Small Market

10% of all AML patients
~1000 patients in USA per year



Total Sales

Cost US\$400,000 per year per patient³

1. <https://www.fda.gov/drugs/fda-approves-gilteritinib-relapsed-or-refractory-acute-myeloid-leukemia-aml-flt3-mutation>

2. <https://clinicaltrials.gov/ct2/show/NCT02421939>

3. <https://www.drugs.com/price-guide/xospata>

